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510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the Mammotome® revolve Vacuum Assisted Biopsy (VAB) System 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990 the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Company:

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Cincinnati, OH 45241
Establishment Registration Number: 3008492462

Contact:

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Date of Submission: August 13, 2012

Proprietary Name: Mammotome® revolve Dual Vacuum Assisted Biopsy (VAB) System

Common Name: Biopsy System

Regulation: 21 CFR 876.1075

Regulatory Class: II

Product Codes: KNW

Classification Name: Biopsy Instrument

Predicate Device: Mammotome® Biopsy System, K033700

Device Description: The Mammotome® revolve Dual Vacuum Assisted Biopsy (VAB) System is a mechanical breast biopsy device indicated to provide tissue samples for diagnostic sampling of beast abnormalities for histologic examination.

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The Mammotome® revolve Dual VAB System is comprised of three primary subsystems:

1) a sterile, single-use probe
2) a reusable holster, and
3) a reusable control unit.

Intended Use: The Mammotome® revolve Dual Vacuum Assisted Biopsy (VAB) System is indicated to provide tissue samples for diagnostic sampling of breast abnormalities.

- The Mammotome® revolve Dual Vacuum Assisted Biopsy (VAB) System is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.
- The Mammotome® revolve Dual Vacuum Assisted Biopsy (VAB) System is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality.

The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpated or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g., fibroadenoma, fibrocystic lesion), the Mammotome® revolve Dual Vacuum Assisted Biopsy (VAB) System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Technological Characteristics:

The Mammotome® revolve Dual Vacuum Assisted Biopsy (VAB) System, facilitates the diagnostic removal of tissue through a combination of vacuum and rotational/translational cutting functions. The Mammotome® revolve Dual Vacuum Assisted Biopsy (VAB) System utilizes the same primary subsystems as identified in the predicate device to achieve its intended use:

1) a sterile single-use probe containing trocar tipped biopsy needle, rotating cutter, specimen collection chambers, and vacuum tubing/valving which enables tissue sample

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acquisition under vacuum, tissue cutting, and tissue transport to the specimen collection chambers;

2) a reusable holster containing the drive motors, gear trains and user activation switches, which provides the basic functionality for the procedure including the rotation, advancement and retraction of the cutting mechanism of the probe, as well as the specimen management system rotation; and
3) a reusable control unit that houses the vacuum pump, power supply, valve actuators, software, user interface touchscreen and control electronics, which provides the primary electrical, electronic, mechanical and vacuum control of the system.

In addition, several accessories are available including remote keypad and footswitch controls, a transport cart and probe guides for various stereotactic (ST) tables.

The Mammotome® revolve Dual VAB System is an updated version of the currently marketed system, incorporating changes to improve efficiency and ease of use, while maintaining the basic technology, functionality and clinical outcomes of the predicate system. Consistent with the configuration of the currently marketed system, the Mammotome® revolve VAB System will be configured for use in multiple imaging modalities, including Stereotactic, Ultrasound, Magnetic Resonance and Advanced Molecular Imaging.

The system relies on software to operate many of its functions including utilization of closed loop control on cutter position. As with the predicate system, the focus of the software is to aid in system set-up and facilitate biopsy functions. The Mammotome® revolve Dual VAB System software has been updated to simplify the touch screen display used to set up the system and create a single button push Biopsy function that transports the tissue sample back to a collection system for retrieval and analysis.

A side-by-side comparison of the marketed and proposed devices is provided below.

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Side-by-Side Comparison to Legally Marketed Device

Device Characteristics	Marketed Device Mammotome® ST System	Proposed Device Mammotome® revolve Biopsy System
Indications for Use	Breast Biopsy/complete, partial removal of imaged abnormality /partial removal of palpated abnormality	Breast Biopsy / complete, partial removal of imaged abnormality /partial removal of palpated abnormality
Probe/Tube Set		
Needle Assembly		
Needle Insertion Method	Fired or Manual	Fired or Manual
Tip Type	Bladed trocar	Bladed trocar
Tip Material	Stainless steel	Stainless steel
Needle Configuration	Dual lumen	Dual lumen
Needle Material	Stainless steel	Stainless steel
Sample Aperture Configuration	Lateral aperture in needle	Lateral aperture in needle
Needle Diameter Sizes	8G, 11G, and 14G	8 G & 10 G
Needle Rotation Method	Manual, Remote Thumbwheel	Manual, Remote Thumbwheel
Probe Housing		
Vacuum Port Attachment (Valve Cartridge)	Yes, tethered to control module	Yes, tethered to Control Module
Specimen Retrieval / Collection Method	Manual	Automatic
Housing Material	Plastic	Plastic
Probe Cutter Subassembly		
Cutting Method	Rotation and translation of inner cutter	Rotation and translation of inner cutter
Tissue Transport Method	Mechanical and Vacuum	Vacuum
Cutter Material	Stainless steel	Stainless steel
Cutter Sealing Mechanism	Yes	Yes
Cutter Sealing Material	Elastomer/Thermoplastic	Elastomer/Thermoplastic
Knockout Sub Assembly		
Knockout Material	Stainless steel	No Knockout / Specimen Retrieval Automatic
Knockout Sealing Mechanism	Yes	
Knockout Sealing Material	Elastomer/Thermoplastic	
Fluid Injection Capability	Yes	
Packaging		
Type	C-film with Tyvek Cover	PETG with Tyvek Cover
Biopsy Site Marking		

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Device Characteristics	Marketed Device Mammotome® ST System	Proposed Device Mammotome® revolve Biopsy System
Marking Access	Through Needle	Through Device
Sterilization		
Method	Cobalt 60 Irradiation	Cobalt 60 Irradiation
Tubing Set		
Physical Properties		
Tubing Material	PVC	PVC with no DEHP
Features		
Attachment to Probe	Luer	Luer
Attachment to control Module	Cartridge with two parallel vacuum lines leading to probe	Cartridge with two parallel vacuum lines leading to probe + Saline line leading to probe
Vacuum Control	Solenoid activated stopcocks	Motor activated Rotary Valves
Sterilization		
Method	Cobalt 60 Irradiation	Cobalt 60 Irradiation
Holster / Cables / Control Module		
Features		
User interface Mechanisms	Buttons on holster, Pedals on Footswitch or Touchscreen	Buttons on holster, Footswitch Pedals, Touchscreen, Keypad
Microprocessor and software with Upgrade Capabilities	Yes	Yes
Display	Yes, LCD display	Yes, LCD display
Translational Cutter Movement	Automatic or Semi Automatic	Automatic
Rotational Cutter Movement	Automatic with cutter advancement	Automatic with cutter advancement
Rotational and Translation Speed control	Yes; Closed-loop control	Yes, Closed loop control
Automated Initialization of Disposable Probe	Yes	Yes
Probe firing capability	Yes	Yes
Motor location	Control Module	Holster
Drive Train Type	Flexible Mechanical Drive Cable	On board Motor and Gear Train
Independent Lateral and Axial Vacuum System	Yes	Yes
Remote Footswitch/Keypad Capability	Yes	Yes

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Performance testing:

To demonstrate substantial equivalence of the proposed device to the predicate device, side-by-side comparison of tissue sample collection, using an in vivo porcine model, was performed. This model has historically been used to evaluate the ability for Mammotome® breast biopsy devices to collect tissue samples.

The Mammotome® revolve Dual Vacuum Assisted Biopsy (VAB) System and the predicate device were each used to obtain tissue samples. Each sample was evaluated against the following criteria:

- Sample weight
- Sampling reliability
- Sample quality

Testing results confirmed that the Mammotome® revolve Vacuum Assisted Biopsy (VAB) System would retrieve a tissue sample comparable to that of the predicate device.

Conclusion: The claim of substantial equivalence of the Mammotome® revolve Dual Vacuum Assisted Biopsy (VAB) System to the predicate system is based on the comparison of the intended use, product technical characteristics, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Underwriters Laboratories, Incorporated
% Mr. Ned Devine
Senior Staff Engineer
333 Pfingsten Road
Northbrook Road, Illinois 60062

November 15, 2012

Re: K123259
Trade/Device Name: Mammotome® revolve Dual Vacuum Assisted Biopsy (VAB) System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: October 16, 2012
Received: October 18, 2012

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K 123259

Device Name: Mammotome® revolve Dual Vacuum Assisted Biopsy (VAB) System

Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number 123259